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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,153	09/21/2005	Patrick Martin Vaughan	1377-0197PUS1	5393
2292 7590 10/05/2007 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			EXAMINER TUNG, JOYCE	
			ART UNIT	PAPER NUMBER
			1637	
			NOTIFICATION DATE	DELIVERY MODE
			10/05/2007	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/519,153	<b>Applicant(s)</b> VAUGHAN ET AL.	
	<b>Examiner</b> Joyce Tung	<b>Art Unit</b> 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/27/04</u> . | 6) <input type="checkbox"/> Other: ____  |

**DETAILED ACTION*****Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-2, and 11-13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 8, 10-12, and 17 of U.S. Patent No. 7,175,982 (issued Feb. 13, 2007). Although the conflicting claims are not identical, they are not patentably distinct from each other because in the claims 1-2 and 11-13 are drawn to a method for characterizing nucleic acid molecules comprising introducing a modified base as a substrate for DNA endonuclease into a target DNA molecule and reacting the nucleic acid with the modified base with the DNA endonuclease to generate an upstream fragment containing the modified base and bearing a 3' hydroxyl group in which the upstream fragment is used as a primer for a subsequent extension reaction (See claim 11). Claims 1-3, 8, 10-12, 17 of U.S. Patent No. 7,175,982 are drawn to the same method as the method recited in claims 1-2 and 11-

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13 except that claims 1 of U.S. Patent No. 7,175,982 recites that the modified base is a substrate for a DNA glycosylase. Nevertheless, claim 3 of U.S. Patent No. 7,175,982 recites that the cleavage is achieved with a 5' AP endonuclease. Therefore, based upon the analysis above, the instant claims and claims 1-3, 8, 10-12, 17 of U.S. Patent No. 7,175,982 (issued Feb. 13, 2007) are ~~released~~<sup>related</sup> as genus-species.

### ***Information Disclosure Statement***

3. The references lined through in PTO-1449 filed 12/27/04 were not considered because the references were not supplied.

### ***Claim Objections***

4. Claims 6-11 and 15-18 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits. Specifically, claims 6-10 and 16-18 depend on claims 3 and 4, which are multiple dependent claims.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 3 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 14 is vague and indefinite because it is unclear what is before described and exemplified.

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- b. Claim 3 is vague and indefinite because it is unclear what is meant by the phrase "partially replace". Clarification is required.

*Claim Rejections - 35 USC § 102*

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Hartley et al. (2002/0072095, issued Jun. 13, 2002).

Hartley et al. disclose a method of introducing a modified base into a target DNA. The modified base is a substrate for a DNA endonuclease. The nucleic acid containing the modified base is cleaved with DNA endonuclease (See [0086]). The dUTP is modified base, which is incorporated into an enzymatic DNA amplification procedure [See [0086]]. Taq polymerase is used (See [0088]). The sequences of the probe oligonucleotides are chemically synthesized (See [0138]).

Hartley et al. do not disclose the modified base is introduced by chemical modification of an existing base as recited in claim 5.

Hartley et al. disclose that the sequences of the probe oligonucleotides are chemically synthesized (See [0138]) containing uracil (See [00134]). It is inherent in the teachings that the modified base is introduced by chemical modification of an existing base.

Based upon the analysis above, the teachings of Hartley et al. anticipate the limitations of the claims.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hartley et al. (2002/0072095, issued Jun. 13, 2002) as applied to claims 1-6 above, and further in view of Dianov et al. (Molecular and Cellular Biology, 1992, pg. 1605-1612).

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The teachings of Hartley et al. are set forth in section 8 above. Hartley et al. do not disclose the limitations recited in claims 11-13.

Dianov et al. disclose a pathway for repair of a dUMP residue in DNA in which an upstream fragment is used as a primer for a subsequent extension reaction (See pg. 1606, fig.1, DNA polymerase step). The extension is carried out using a DNA polymerase or a DNA ligase (See pg. 1606, fig. 1)

One of ordinary skill in the art would have been motivated to apply the polymeration step and ligation step of Dianov et al. in the method of Hartly for characterizing nucleic acid molecules because the limitations of claims 11-13 were used in the pathway for repair of a dUMP residue in DNA and the repair is efficiently done (See pg. 16, column 1 last paragraph). It would have been prima facie obvious to apply the limitations as recited in claims 11-13.

11. Claims 7-10 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hartley et al. (2002/0072095, issued Jun. 13, 2002) as applied to claims 1-6 above, and further in view of Barany et al. (2003/0148283, issued Aug. 7, 2003).

The teachings of Hartley et al. are set forth in section 8 above. Hartley et al. do not disclose the limitations recited in claims 7-10 and 15-18.

Barany et al. disclose a method to detect nucleic acid differences using combined endonuclease cleavage and ligation reactions (See [003]). The method is for identifying a mutant nucleic acid sequence differing by one or more single-base changes, insertions, or deletions, from a normal target nucleotide sequence and scanning mutation or polymorphisms (See [0016], [0022]). The endonuclease is endonuclease V that is thermostable (See [0020] & [0097]). The

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labeled oligonucleotide primer is a complementary strand of a mutant nucleic acid sequence (See pg. 35, claim 1).

One of ordinary skill in the art would have been motivated to apply the thermostable endonuclease V as taught by Barany et al. in the method of Hartly et al. for characterizing nucleic acid molecules because the method of Barany et al. has proven effective in identifying unknown frameshift, nonsense and missense mutations (See [0022]). It would have been prima facie obvious to apply the limitations of claims 7-9 and 15-18 for characterizing nucleic acid molecules.

#### **Summary**

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

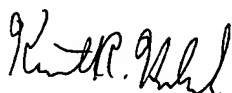
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Joyce Tung  
September 28, 2007

  
KENNETH R. HORLICK, PH.D  
PRIMARY EXAMINER

10/1/07